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Section I 510(k) Summary of Safety and Effectiveness

Applicant:

AUG - 4 2006

Draeger Medical Infant Care Inc
330 Jacksonville Road
Hatboro, Pa. 19040
Registration No: 2510954

Contact Person:

Monica Ferrante
Ph 215-682-8691
Fax 215-682-8689

Device trade/proprietary name:

Versalet 7700 Care Center

Device common/usual/classification name:

Infant Incubator / Infant Radiant Warmer

Classification:

General Hospital
21 CFR 880.5400, and 21 CFR 880.5130

Performance Standards:

None applicable

Predicate Device:

K993051 Versalet 7700 Care Center
K993407 Giraffe OmniBed

Device Description

The Versalet™ 7700 Care Center is a warming device that combines the heating technologies of both incubators and radiant warmers into one product. The Versalet™ 7700 Care Center provides thermal isolation through a convective air system with canopies and side panels forming an enclosure that isolates the air surrounding the infant from the room air, much the same as a traditional infant incubator. The Versalet™ 7700 Care Center offers access to the infant in the incubator mode by allowing the caregiver to open port holes or side panels. If

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more access is needed, the device can then be transitioned into a radiant warmer device by opening the canopies and raising the over head arm. This allows full access to the infant. The over head arm contains two infrared heaters that provide radiant heat only when the canopies are opened and the over head arm is fully raised. Thus the Versalet™ 7700 Care Center offers the caregiver excellent access while providing good thermal stability. While the device is in the transition mode from incubator to warmer there is a continued supply of convective heat to minimize the heat loss during this period.

Intended Use

The Versalet 7700 Care Center is a mobile, caster mounted, neonatal device, which is used to assist in maintaining an infant's skin temperature and thermal environment. The device accomplishes this using radiant or convective heat. Accessories and options to the device permit environmental control and monitoring and may include optional features such as humidification and in-bed scale. It is intended for inpatient use in maternity nurseries, and neonatal care environments of hospitals or other healthcare facilities.

Technological Characteristics

The new device is equivalent to currently marketed devices with regards to materials, construction and basic design. There are no new questions of safety or effectiveness with regards to the new device. The new device and currently marketed devices are considered substantially equivalent. All issues concerning safety and effectiveness of the Versalet 7700 Care Center are addressed in the design, labeling and manufacture of the device.

Performance Data

The Versalet 7700 Care Center technology is well established in clinical practice, therefore, pre-clinical and clinical testing are not required to establish the performance of the device. Testing to the relevant international standards and product specifications to include hardware and software verification and validation satisfies the requirements of the Quality System Regulation Design Controls.

Sterilization Information

The Versalet 7700 Care Center, nor any of its components are intended for sterilization. The User Manual provides information for cleaning and disinfection of the system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 2006

Ms. Monica Ferrante
Director of Regulatory Affairs
Draeger Medical Infant Care, Incorporated
330 Jacksonville Road
Hatboro, Pennsylvania 19040

Re: K053399
Trade/Device Name: Versalet 7700 Care Center
Regulation Number: 880.5400
Regulation Name: Neonatal Incubator
Regulatory Class: II
Product Code: FMZ, FMT
Dated: July 14, 2006
Received: July 17, 2006

Dear Ms. Ferrante:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Susan Runner

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K053399

Device Name: Versalet 7700 Care Center

Indications For Use:

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This device is not intended for home use.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rld C Chan for ADW 8/4/2006

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K053399